broader community of practicing urologists. To the extent that technology substitution occurs, the use of URS might be expected to change after the expansion of lithotripter ownership.

MATERIAL AND METHODS

Data Source and Subjects

For the present study, we used data from the Healthcare Cost and Use Project's State Ambulatory Surgery Database (SASD). The Michigan SASD files capture 96% of hospital-based surgeries in a given year performed on the same day in which patients are admitted and released.[11] The completeness of the SASD has been validated through alternative sources of comparative data.[11]

Using the *Current Procedural Terminology* codes (52320, 52325, 52330, 52335, 52336, 52337, 52351, 52352, and 52353), we identified patients undergoing URS from 2004 to 2007. Before 2005, the SASD's state partner did not supply outpatient information from 2 health systems in Michigan, which accounted for 4% of all discharges. Therefore, we limited our study population to those discharges from hospitals with complete reporting during the study interval, as determined by the SASD's unique hospital identifier.

Primary Outcome

We then calculated the annual state-level rates of URS use. The numerator for our rate calculation was the number of times that URS was performed in Michigan during a specific calendar year. The denominator represented the number of people living within Michigan that year. We obtained our population estimates from the *Dartmouth Atlas of Health Care*.[12] We adjusted all rates of URS by age and sex to the 2000 US population using direct standardization and expressed them per 100 000.

Statistical Analysis

From 2005 to 2006, United Health Systems and American Kidney Stone Management formed Michigan subsidiaries. Although the individual shares have not been publicly disclosed, personal communications with 1 of the 2 lithotripsy providers suggests that more than one half of urologists in the state (the American Urological Association database currently shows 390 practicing urologists members/nonmembers) elected to participate in these partnerships. Owing to Michigan's stringent Certificate of Need requirements,[13] urologist investment in lithotripsy units had previously been limited. From this information, we defined 2 periods—before (2004) and after (2007) the expansion of lithotripter ownership.

As an initial analytical step, we examined the differences between patients who underwent URS across the 2 periods. We compared a variety of demographic characteristics (eg, patient age, sex, race, primary payer, socioeconomic status, and comorbidity status). We used a composite measure to assess socioeconomic status at the patient zip code level,[14] producing 3 equal-size groups (terciles) that ranged from low to high. To assess comorbidities, we derived a weighted Charlson score for each patient.[15] For these comparisons, we used parametric and nonparametric statistics, as appropriate. Next, we plotted the rates of URS use in Michigan by calendar year. We fitted a linear regression model to evaluate for significant changes in URS use over time. Finally, to account for potential confounding by national trends in URS practice patterns, we used linear regression analysis to compare the trends in the rates of URS use in Michigan with those from Florida during the study interval. Florida was selected for comparison because of its high number of annual ambulatory surgery discharges among states in the SASD.[16] In addition, Florida does not subject medical facilities to Certificate of Need requirements,[17] yielding a likely stable penetration of physician-owned lithotripsy units during this period compared with Michigan.

For all statistical inferences, we performed 2-sided significance testing and set a type I error rate at 0.05, using the SAS system, version 9.2 (SAS Institute, Cary, NC). The University institutional review board of Michigan deemed that our study on these existing, publicly available data was exempt from its oversight.

RESULTS

In 2004 and 2007, 5857 and 6294 URSs were performed at hospital-based outpatient departments, respectively (Table 1). Compared with patients treated before ownership expansion, those who underwent URS after ownership expansion were older (50.4 ± 16.0 years vs 51.3 ± 16.3 years; $P < .001$). They were also less likely to be white (93.6% vs 89.1%; $P < .001$) or have private health insurance (70.2% vs 66.8%, $P < .001$). In addition, they were sicker (eg, the proportion of patients with a Charlson score of zero fell from 84.3% to 80.4%; $P < .001$).

As Figure 1 illustrates, the rates of URS use in Michigan remained relatively flat between 2004 and 2007 ($P = .129$ for temporal trend). Although the absolute rates of URS use in Michigan were greater than those in Florida throughout the study interval (Fig. 1), no differences were found in the rate of change of URS use between the 2 states during the study period ($P = .479$).

COMMENT

During the past decade, physician investment in lithotripsy ventures has become an important practice component for most urologists in the United States.[3] Although these financial arrangements might incentivize providers to perform more SWL,[4,5] the potential spillover effects on competing technologies (ie, URS) remain unclear. During a period of ownership expansion of lithotripsy units among urologists in Michigan, we found that the rates of URS use remained stable during the study interval. As a secondary finding, patients treated with URS after lithotripter ownership expansion were older

Table 1. Demographic patient characteristics stratified by URS use before and after expansion of lithotripter ownership in Michigan

Characteristic	Before Ownership Expansion	After Ownership Expansion	*P* Value
Procedures (n)	5857	6294	
Patient age (y)	50.35 ± 16.02	51.34 ± 16.34	< .001
Women (%)	43.7	45.10	.121
Race (%)			< .001
White	93.6	89.1	
Black	4.1	5.9	
Hispanic	0.7	0.6	
Asian	0.6	0.6	
Other	1.0	3.8	
Primary payer (%)			< .001
Medicare	21.7	23.6	
Medicaid	5.0	5.8	
Private	70.2	66.8	
Self-pay	2.0	2.8	
Other	1.1	1.0	
Socioeconomic status (%)			.388
Low	33.3	32.5	
Medium	31.8	32.9	
High	34.9	34.6	
Charlson score (%)			< .001
0	84.3	80.4	
1	10.8	13.4	
2	3.2	4.7	
≥3	1.7	1.5	

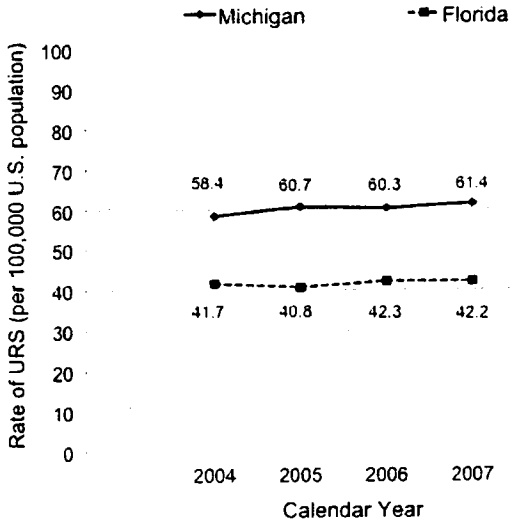

Figure 1. Trends in rates of URS use over time for Michigan and Florida.

and sicker and less likely to have private insurance than the patients treated with URS before the availability of these partnerships.

Although ownership arrangements have been linked to increased procedure use,[4-10] the extent to which the increased use might influence substitutable technologies remains largely unknown. Previously, Mitchell et al[8] analyzed medical claims from the largest worker's compensation insurer in Oklahoma. After identifying episodes of care for injured workers with a primary diagnosis of back/spine disorders, she compared the practice patterns of physician owners of specialty hospitals in Oklahoma, before and after their acquisition of ownership, to the practice patterns of physician nonowners who managed similar cases. She demonstrated that the referral rate for complex spinal fusion grew much more rapidly for owners than for nonowners. Although the use of simple spinal fusion—a less profitable, yet comparably effective, procedure[18]—grew among patients treated by nonowners, the use of this procedure decreased among owners. In contrast to Mitchell's findings, we observed stable rates of URS after the expansion of mobile lithotripter ownership, suggesting that patients in Michigan continued to receive URS when indicated despite the financial incentives for urologists to perform SWL.

Although the absolute rate of URS remained stable, the profile of patients undergoing this procedure changed during the study interval. Compared with patients treated with URS in 2004, those who underwent URS in 2007 tended to be older and sicker. There were also lower proportions of white patients and those with private health insurance. This appeared to counterbalance the shifting patient demographic (ie, younger, healthier, and wealthier patients) observed among those treated with SWL in Florida during a period of increased urologist ownership of ASCs.[4] Taken together, these changes are consistent with the migration of healthier and more profitable patients from hospitals to physician-owned facilities.[19] Although we could not exclude the possibility that this might also reflect more global changes in the population of patients with urolithiasis,[20] our findings suggest that physician ownership might also influence treatment decisions in the context of other patient considerations (eg, insurance status, pre-existing comorbidity).

Our study has several caveats. Our analysis was largely based on the assumption that SWL and URS are substitutable technologies. Although both trial and observational data suggest comparable efficacy for a variety of clinical situations,[21,22] several nonclinical factors, which we could not measure with administrative data (eg, physician training, patient preference), could also affect treatment selection.[23] While certain clinical scenarios might exist in which 1 technique would be preferable to the other, both SWL and URS are considered first-line treatment options for urolithiasis by both the American Urological Association and the European Association of Urology, further supporting our assumption that these surgical approaches are largely substitutable.[22] Further, we could not exclude the possibility of technology substitution between SWL and percutaneous nephrolithotomy or medical expulsive therapy, but the potential effect from technology substitution with these modalities would likely be marginal compared with URS, given their specific indications and the reportedly low use of these modalities during the study interval.[24,25] Additionally, because the Michigan SASD files provide discharge-level data, we were unable to account for previous stone treatment. As such, it is possible that the observed URS trend reflects a decrease in first-line URS use and an increase in secondary URS use for SWL treatment failure. However, a substantially greater increase in SWL use than that previously observed after ownership expansion would be needed to conceal the occurrence of technology substitution from the reported rates of treatment failure and salvage URS after SWL.[4,5,21,22]

Our analysis was also limited by the exclusion of ASC discharges from the Michigan SASD files. Because SWL is commonly performed in ASCs, we were unable to assess for concurrent changes in SWL use during this period of ownership expansion. However, the link between physician ownership and increased SWL rates has been previously described,[4] and we would expect similar increases in Michigan. In contrast, URS is performed predominantly in hospital-based outpatient departments, even among states with more lenient Certificate of Need requirements.[26] Moreover, ownership expansion in the present study pertained to a specific procedure rather than an entire surgical facility. Thus, the absence of ASC discharges is unlikely to have affected the validity of our findings as it relates to URS, especially in Michigan, where the establishment of ASCs is more restricted.

In addition to these considerations, the association between the rates of URS and the expansion of lithotripter ownership could be attenuated by the temporal trends affecting all states similarly. Because the annualized national trends data for URS during the study interval were lacking, we compared URS use in Michigan with the rates from Florida during the same period. Despite the absolute difference in URS rates between the 2 States, which likely reflects differing practice patterns or stone prevalence, we noted no difference in overall trends, addressing the potential bias from temporal changes in the surgical treatment of urolithiasis. We also lacked surgeon identifiers and were unable to measure the change in frequency of URS use among individual urologists who obtained ownership shares in SWL compared with those who did not. Additional studies are needed to assess the effect of ownership expansion and technology substitution at a physician level.

These limitations notwithstanding, our findings have direct implications, not only on urologists' ownership of lithotripters, but also on their investment in ancillary services technology and specialty care, facilities. Recently, high-profile articles in the lay press have raised questions about urologists who have begun buying multimillion dollar intensity-modulated radiotherapy equipment and software.[27,28] Given the substantial profit margin seen with intensity-modulated radiotherapy, critics have warned that urologist ownership could lead to its overuse.[29,30] Additionally, they have argued that urologist ownership could lead to subsequent decreases in the use of other first-line therapies for organ-confined prostate cancer, including radioactive seed implants, radical prostatectomy, and active surveillance (ie, technology substitution). These concerns have been voiced before the Centers for Medicare and Medicaid Services.[31] Although the profile of patients receiving specific treatments could change, the results of our analysis might, for the time being, help allay the latter concern regarding the use of substitutable technologies, at least at a population-level.

CONCLUSIONS

The expansion of lithotripter ownership in Michigan was not associated with decreased rates of URS but might have influenced treatment decisions among certain patient groups. Despite recent concerns, physician ownership does not appear to result in technology substitution to a substantial degree, at least as it pertains to lithotripter ownership. Although reassuring, future studies that focus on the practice patterns of individual urologists during periods of ownership expansion are still needed to better characterize the effect of physician ownership.

References

1. Pham H, Devers K, May J, et al. Financial pressures spur physician entrepreneurialism. *Health Aff.* 2004;23:70-81.
2. Levin DC, Rao VM, Parker L, et al. Ownership or leasing of MRI facilities by nonradiologist physicians is a rapidly growing trend. *J Am Coll Radiol.* 2008;5:105-109.
3. O'Leary M, Baum N, Bohnert W, et al. 2003 American Urological Association Gallup survey: physician practice patterns, cryosurgery/brachytherapy, male infertility, female urology and insurance/professional liability. *J Urol.* 2004;171:2363-2365.
4. Hollingsworth JM, Krein SL, Birkmeyer JD, et al. Opening ambulatory surgery centers and stone surgery rates in health care markets. *J Urol.* 2010;184:967-971.
5. Hollingsworth JM, Ye Z, Strope SA, et al. Urologist ownership of ambulatory surgery centers and urinary stone surgery use. *Health Serv Res.* 2009;44:1370-1384.

6. Hollingsworth JM, Ye Z, Strope S, et al. Physician-ownership of ambulatory surgery centers linked to higher volume of surgeries. *Health Aff.* 2010;29:683-689.
7. Mitchell JM, Scott E. Physician ownership of physical therapy services: effects on charges, utilization, profits, and service characteristics. *JAMA.* 1992;268:2055-2059.
8. Mitchell JM. Do financial incentives linked to ownership of specialty hospitals affect physicians' practice patterns? *Med Care.* 2008; 46:732-737.
9. Nallamothu BK, Rogers MAM, Chernew ME, et al. Opening of specialty cardiac hospitals and use of coronary revascularization in Medicare beneficiaries. *JAMA.* 2007;297:962-968.
10. Mitchell JM, Sunshine JH. Consequences of physicians' ownership of health care facilities—joint ventures in radiation therapy. *N Engl J Med.* 1992;327:1497-1501.
11. Busch J, Steiner C. Evaluation of the State Ambulatory Surgery Databases Available through the HCUP Central Distributor. 2004. Available from: http://www.hcup-us.ahrq.gov/reports/methods.jsp. Accessed October 13, 2010.
12. Wennberg J. *Dartmouth Atlas of Health Care.* Chicago: American Hospital, Inc.; 1996.
13. Conover C, Sloan F *Evaluation of Certificate of Need in Michigan,* vol. 2. Durham: Terry Sanford Institute of Public Policy, Duke University; 2003.
14. Diez Roux AV, Merkin SS, Arnett D, et al. Neighborhood of residence and incidence of coronary heart disease. *N Engl J Med.* 2001;345:99-106.
15. Deyo RA, Cherkin DC, Ciol MA. Adapting a clinical comorbidity index for use with ICD-9-CM administrative databases. *J Clin Epidemiol.* 1992;45:613-619.
16. AHRQ. Introduction to the HCUP State Ambulatory State Database (SASD), June 13. Available from: http://www.hcup-us.ahrq.gov/sasdoverview.jsp. Accessed October 13, 2010.
17. Florida HCoS. Certificate of Need. 2008. Available from: http://www.healthcouncil.org/certificateofneed.asp. Accessed October 13, 2010.
18. Mitchell JM. Utilization changes following market entry by physician-owned specialty hospitals. *Med Care Res Rev.* 2007;64:395-415.
19. Shactman D. Specialty hospitals, ambulatory surgery centers, and general hospitals: charting a wise public policy course. *Health Aff.* 2005;24:868-873.
20. Stamatelou KK, Francis ME, Jones CA, et al. Time trends in reported prevalence of kidney stones in the United States: 1976-1994. *Kidney Int.* 2003;63:1817-1823.
21. Pearle MS, Lingeman JE, Leveillee R, et al. Prospective, randomized trial comparing shock wave lithotripsy and ureteroscopy for lower pole caliceal calculi 1 cm or less. *J Urol.* 2005;173:2005-2009.
22. Preminger G, Tiselius H-G, Assimos D, et al. Guideline for the management of ureteral calculi. *J Urol.* 2007;2007:2418-2434.
23. Bandi G, Best SL, Nakada SY. Current practice patterns in the management of upper urinary tract calculi in the north central United States. *J Endourol.* 2008;22:631-636.
24. Matlaga BR, for the American Board of Urology. Contemporary surgical management of upper urinary tract calculi. *J Urol.* 2009; 181:2152-2156.
25. Hollingsworth JM, Wolf JS, Faerber GJ, et al. Understanding the barriers to the dissemination of medical expulsive therapy. *J Urol.* 2010;184:2368-2372.
26. Strope SA, Wolf JS, Faerber GJ, et al. Changing practice locations for upper urinary tract stone disease. *J Urol.* 2009;182:1005-1011.
27. Saul S. Profits and questions as doctors offer prostate cancer therapy. *The New York Times.* New York: New York Times Company; 2006:A1, C7.
28. Carreyrou J, Tamman M. Secrets of the system: a device to kill cancer, lift revenue. *The Wall Street Journal.* New York: Dow Jones & Company; 2010; available from: http://online.wsj.com/article/SB10001424052748703904804575631222900534954.html.
29. Anscher MS, Anscher BM, Bradley CJ. The negative impact of stark law exemptions on graduate medical education and health care costs: the example of radiation oncology. *Int J Radiat Oncol Biol Phys.* 2010;76:1289-1294.
30. Falit BP, Gross CP, Roberts KB. Integrated prostate cancer centers and over-utilization of IMRT: a close look at fee-for-service medicine in radiation oncology. *Int J Radiat Oncol Biol Phys.* 2010;76:1285-1288.
31. Centers for Medicare and Medicaid Services (CMS), HHS. Medicare program: changes to the hospital inpatient prospective payment systems and fiscal year 2009 rates; payments for graduate medical education in certain emergency situations; changes to disclosure of physician ownership in hospitals and physician self-referral rules; updates to the long-term care prospective payment system; updates to certain IPPS-excluded hospitals; and collection of information regarding financial relationships between hospitals. Final rules. *Fed Regist.* 2008;73:48433-49084.

EDITORIAL COMMENT

Urologists are coming under close scrutiny by third-party payers and the government for their ownership of ancillary services, including laboratory services such as blood work and pathology, imaging equipment, treatment facilities including surgicenters, lithotripters, and intensity-modulated radiation therapy. These relationships have not gone unnoticed in the lay press and are frequently recounted on the front pages of the nation's more prominent newspapers. In this article, Hollingsworth and colleagues at the University of Michigan looked at whether urologist investment in lithotripters in the state of Michigan changed practice patterns, specifically with regard to ureteroscopy (URS) and shock wave lithotripsy (SWL). The authors queried the state's ambulatory surgery database to perform their study. I found it interesting that more than half of the urologists in the state of Michigan participated in these limited SWL partnerships. Interestingly, the rate of URS compared with SWL did not change after urologists became financial partners. There were some differences in race, insurance, and comorbidities that were noted between the URS and SWL groups that were not well explained but may be simply because the uninsured may be seen more often at academic institutions or that older patients are more often anticoagulated, making them better suited for ureteroscopy. Interestingly, when compared with Florida, URS was more prevalent in Michigan, But similar differences would probably be noted for surgery compared with external beam radiation or brachytherapy for the treatment of prostate cancer.

Urologists have always been at the forefront of medical and financial innovation. I have always found it interesting to note the national and international trends in the diagnosis and treatment of all urological disorders. Urologists owe it to their field, their forefathers, and, most importantly, their patients to uphold the values of proper patient care while pushing the envelope with innovative medical advances that have made this specialty great. Under increasing governmental scrutiny, the onus will be on urologists to show that they have their patients—not their pocketbooks—in mind when they select a treatment. Hollingsworth and colleagues should be applauded for asking the tough but obvious questions for which everyone wants to know the answers.

Robert B. Nadler, M.D., Northwestern University Feinberg School of Medicine, Chicago, Illinois

doi:10.1016/j.urology.2011.07.1420
UROLOGY 78: 1291, 2011.

Dear Ms. Engleman:

I am writing again, because I want to be clear about the basis of my complaint about UESWL. It is about the nature and critical importance of patient ***consent***. If the FDA wants to hedge an issue as important as safety of a so-called "promising" technology, then fine, but then the medical community MUST BE ENTIRELY FORTHRIGHT about it with their patients. Physicians will always make professional judgments in offering therapies to their patients, but when there are alternatives to a therapy a physician is promoting, not offering clear, honest, and comparative information about both risks and benefits of all available treatments due to obvious personal non-clinical preferences, i.e. improper financial incentives, is a very serious breach of trust for patient care. Deliberately avoiding calculation of serious risks based on known, established problems with a procedure/technology is proving harmful beyond measure. Government authorities turning a blind eye to this is a very dangerous and slippery slope.

For example: Were a patient to have a tumor, polyp, or bowling ball lodged in their maxillary sinus cavity, it may be possible to perform surgery through the nose to remove it, with inherent risks. So, let's say a fancy new technology came along that eliminated the need to perform surgery, where a device was positioned over the sinus cavity externally that could emit rays that would effectively break up the tumor, polyp, or bowling ball, so that when finished all the patient need do is with a few honking blows of the nose expel the remains of their problem onto a handkerchief or tissue. Voila! "Non-Invasive!"

Now then, it turned out that one of the unpredictable problems with this new technology was that it was also found to damage, say, the optic nerve or retina of the eye, or even cause some slight brain damage. Sometimes blindness in the affected eye was immediate, but sometimes it took a while for the problem to reveal itself. Like with UESWL, the physicians performing this new sinus treatment became non-provider "investors" in the technology and based the "structures" of their "arrangements" entirely on profiting from the volume of patients they treated. What if you were the patient? Would you want to be informed? Or would you simply let the doctor decide without knowing his ulterior motivations?

With UESWL, the judgment made by urologists, the rationalizing story they tell themselves over and over again is that "patients can survive with one kidney," so they never fully or accurately disclose the actual risk to their patients from pure fear of harm to their "passive income." (And we know they never accurately disclose what it might be doing to the pancreas, spleen, etc.) My point is this: What if these hypothetical ENT sinus therapy "investor-physicians" made that same sort of judgment without disclosing the risk of blindness or brain damage because they also knew that "patients can survive with one eye or a little brain damage?" In both cases of UESWL and the hypothetical new sinus technology, patients would be unwittingly consenting to a physician's judgment that was dangerously flawed and biased to whether or not a patient would "survive" with one kidney or eye, rather than engaging the patient without bias in a proper contract for consent based on factual science or lack thereof.

Patient consent is in fact a CONTRACT, an agreement. But, it is entirely based on proper HONEST representations just like any other contract – it is insane that we are permitting the gross misrepresentations about this UESWL procedure to continue. It is easily and obviously a breach of CONTRACT with these millions of patients. It is absolutely INSANE.

Now, I just want to say this to you: Would the FDA consider this new hypothetical sinus technology safe? Or would the FDA require those performing the procedure to fully and honestly disclose the risk of blindness to the patient?

Whether a kidney or eye, we all know we could "survive" with one – but the real judgment should be made when patients decide whether or not they wish the quality of their lives to be so reduced in this manner or whether or not they prefer an alternative treatment. And when it comes to the pancreas in the case of UESWL, we have only one. This is about utilizing a valid body of honestly proven FACTS and representations, and then patients CONSENTING to them, unvarnished – this is my point. THE FACTS MATTER and "safety" is not only whether or not a patient can merely "survive" in some sort of reductionist manner. Just how do you propose to measure "survival?" Five years? Ten? Twenty? Would it depend on the age of the patient consenting to the procedure? What risk did Fen Phen pose, for example, when we figured out it was wrecking heart valves and muscle? A patient could "survive" with a valve replacement or a transplant... but was that safe?

And so this is my point. I have watched now over all these years this very grave medical injustice continuing to be leveled against the public, while the perpetrating urologists profit in their so-called "lawfully structured" financial operations that are in all honesty full blown kickbacks paid within cooperative arrangements for their patient referrals. What on earth makes these urologists so special that they are permitted to do this to people?

Are you going to do something? This whole scam is deeply unjust on a scale so massive that it is difficult to measure. It is an appalling, disgraceful, breach of medical trust with the American public, costing life, life quality and health to hundreds of thousands without their knowledge, and billions of dollars from the system to those who have been duped by a con that has reduced us to unwitting pawns in this slimy covert extortion scheme. It is disgusting and truly frightening that it has been allowed to continue without remotely appropriate legal boundaries and proper scientific measure.

Does all this mean it will be ***okay*** in the future if we start leveling one-eyed blindness across the country because people could "survive" with the other eye? Do you know how ludicrous this sounds? Now then, is it ***okay*** to knock off the function of one kidney (or spleen, or pancreas!) because people can "survive" with the other kidney (or for a while on dialysis?!)?

These urologists have not proven to be FAIR judges or practitioners of honest medicine, and have been hiding a very deadly secret for decades in order to protect their little "side" businesses. They are being permitted to just hide within the massive "herd" they have created for their own protection, paying politicians off along their merry way.

Please, I am begging you; the least you can do is give the public FAIR WARNING about what is and what has been happening to them for the past thirty years!

Please. And thank you.

Sincerely,

11-CV-10090

HON VICTORIA ROBERTS

000098

Anne Mitchell

Sent via email

6/26/14

Dear Ms. Engleman:

I recently reviewed a letter I sent to you on February 10, 2014 (attached), and am unsure whether I was clear enough about my most important concerns as I'd conveyed them to you. So, I am writing you today in attempt to clarify my point.

In the article I'd mentioned (attached), the urologists obtained certain data from *State Ambulatory Surgery Database (SASD)*. These doctors carefully selected the only the data they felt would serve to support the conclusions they had clearly already set out to reach from the beginning. Had they chosen to portray the reality and truth of this clinical situation, they could easily have used the *SASD* database to compare the numbers all around as they should have in order to have painted an honest picture of what happens in these lithotripsy "structured arrangements" before and after. In a truthful and statistically significant manner they should have portrayed (1) the volume of patients treated with UESWL before and after being financially incented to perform UESWL; (2) the volume of patients treated with URS before and after, and of utmost clinical importance (3) the volume of patients treated first by UESWL and subsequently with URS (as a remedy for UESWL failure) before and after. To be honest and forthright they should have considered and described the increase in cost to the system as a result. All these data were available to them through the SASD and the Michigan Department of Community Health Certificate of Need Section Survey Data (this survey data remains and past surveys can be requested of the MDCH CON – go to www.michigan.gov/con and click on "Annual Surveys"). But rather than draw truthful and meaningful conclusions, they chose to deceive the medical community about the truth. The truth, had they chosen it, would have clearly demonstrated the distinct and glaring corrupting of medical judgment by kickbacks at dramatically increased consumer cost in both life and treasure.

This Michigan information is very important because of the timing of it – it is still possible there to gain the knowledge of what happens to patients before and after kickback "arrangements" are "structured," and implemented. In nearly all other places in the U.S., this ship has sailed long ago – these "arrangements" have been made in most other places as far back as 1984. In Michigan today you can see the pattern of what happened elsewhere long ago. And it shows a sobering and frightening paradigm example of how medical judgment is swiftly corrupted and overtaken by greed – this greed and improper judgment goes into overdrive *especially* and even more so when "arrangements" are purported to be properly "structured." Unfortunately for the rest of us peons this is now an entrenched, highly organized, and collective greed that is intentionally protecting critical information about the truth concerning highly questionable safety of UESWL.

These urologists, on a national scale, collaborated and colluded in this UESWL scheme from the beginning and the patterns of this can easily be seen throughout the medical literature if you know what you are looking at. By being successful in absence of oversight or scrutiny, they have patterned many other "business" schemes in the same manner – laser, cryotherapy, brachytherapy, IMRT, and more. They came together in their double secret society, *The American Lithotripsy Society* (cleverly disguised as a lithotripsy education and "credentialing" organization), and with the booty heisted from healthcare consumers hired Tom Mills (the powerful DC attorney/lobbyist known for his lobbying efforts on behalf of Phillip Morris). The highly connected Mills and his firm, *Winston Strawn*, took advantage of hiring John McMickle away from his position as Senator Chuck Grassley's Chief of Staff. A very clear line to the Senate Finance Committee (Healthcare Subcommittee) was drawn and the talented Mr. Mills commanded the huge win by carving out that legislative *"Fair Market Value" Exception* within the *Anti-Kickback* law. *Voila!* But can anyone really ever define the term *"Fair Market Value?"* How clever and deceitful - therein lays the rub. So, brilliant as he is, Mr. Mills waved his magic wand, and has made it apparently lawful to get away with murder, as it were, as long as the "arrangements" are properly "structured." There is no justice in this for the American people. What happened here is frightening and grotesque and wrong and *illegal*. It is *RICO* on steroids.

It has become abundantly clear to me that so far no one of any authority to do something cares much about what has truthfully happened here to millions of people. The legislation for greed to trump medicine has been granted, and the millions of patients with no knowledge of how to fathom medical/legal subtleties are left entirely to fend for themselves. It is so wrong and so disgusting. It defies any human decency whatsoever.

What is the *"Fair Market Value"* of a kickback that corrupts sound medical judgment and conceals highly dangerous practices without disclosing risk? Can the FDA explain this?

It is germane to understand just how comprehensive and far their greed and the protection of this greed go. All the meetings are careful, small, private, clandestine, and spare, in hushed tones behind closed doors. Everyone is sworn to secrecy. These players gain their wealth by virtue of the volume of patients they treat and retreat with UESWL. They falsify medical research by means of lies of omission. They call it "protecting the evidence." They have their "highly trained technologists" totally hamstrung by paying them, as well, by the volume of patients that are treated. They have effectively made these technologists financially dependent on keeping their mouths shut about the improper use of the technology, whether it is by unnecessary or improper treatments or re-treatments. The urologists feel very confident by these "arrangements" that they are protected and that their medical judgment will never be questioned – there is code of silence that is comprehensively financially devised to conceal grave harm. And no one else of any authority is watching what is going on as the public has been duped and swindled in unspeakable ways.

It is my distinct understanding that our HHS OIG has historically been concerned that the amount of payment made to referring physicians is based on the volume of business generated by the referring physicians. The law has been designed now to teeter on the edge of just what that means, apparently. What about the kinds of commercially unreasonable payments that serve to corrupt medical judgment, show clear evidence of overutilization, and dramatically increase costs to taxpayers and Federal Healthcare programs, and vaporize competition? Have our government officials been "Jedi-mind-tricked?" Or is it just easier to turn a blind eye? What about when there is clear evidence of medical deception, harm, improper use, collusion, and unmistaken cooperation between competitive businesses to fix prices? What if properly "structured" "arrangements" are killing people, whether immediately or by damaging their health irreparably and causing premature death? What about all the lies…*all* the lies? What precisely is "improper" medical judgment, especially when there are clear choices and alternative treatments? In reality, does anything go – just how far do physicians get to ad-lib for kickbacks without oversight or accountability?

Anyway, you catch my drift. Thank you for your service.

Sincerely,

Anne Mitchell